Test Type: 1-YEAR

Route: SKIN APPLICATION

Species/Strain: Mouse/SKH-1/NCTR

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Compound: Aloe phototoxicity studies

CAS Number: ALOEPHOTOTOX

Date Report Requested: 10/23/2014 Time Report Requested: 13:01:44

First Dose M/F: NA / NA

Lab: NCTR

C Number: C20406

Lock Date: 12/02/2008

Cage Range: All

Date Range: All

Reasons For Removal:

Removal Date Range:

Treatment Groups: All

Study Gender: Female

PWG Approval Date NONE

Species/Strain: Mouse/SKH-1/NCTR

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Type: 1-YEAR

Test Compound: Aloe phototoxicity studies

Route: SKIN APPLICATION

INTEGUMENTARY SYSTEM

Cyst Epithelial Inclusion

Skin, Control

Abscess

CAS Number: ALOEPHOTOTOX

First Dose M/F: NA / NA Lab: NCTR

(36)

4 (11%)

(36)

1 (3%)

1 (3%)

Date Report Requested: 10/23/2014 Time Report Requested: 13:01:44

SKH-1/NCTR Mouse FEMALE NOCREAM NO SSL VEHICLE NO SSL ALOGEL6% NO WHLEAF6% NO CHARCL6% NO AEMOD_ H NO_ SSL SSL SSL SSL **Disposition Summary Animals Initially In Study** 36 36 36 36 36 36 **Early Deaths** 7 2 **Moribund Sacrifice** 5 2 3 **Natural Death** 1 2 1 **Survivors Moribund Sacrifice** 2 1 2 **Terminal Sacrifice** 30 28 30 33 32 33 1 1 Harvest **Animals Examined Microscopically** 36 36 36 36 36 36 **ALIMENTARY SYSTEM** None CARDIOVASCULAR SYSTEM None **ENDOCRINE SYSTEM** None **GENERAL BODY SYSTEM** None **GENITAL SYSTEM** None HEMATOPOIETIC SYSTEM None

(36)

3 (8%)

(36)

1 (3%)

3 (8%)

(36)

3 (8%)

(36)

2 (6%)

6 (17%)

a - Number of animals examined microscopically at site and number of animals with lesion

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Type: 1-YEAR Route: SKIN APPLICATION Test Compound: Aloe phototoxicity studies **CAS Number:** ALOEPHOTOTOX

Species/Strain: Mouse/SKH-1/NCTR

Date Report Requested: 10/23/2014 Time Report Requested: 13:01:44 First Dose M/F: NA / NA

Lab: NCTR

SKH-1/NCTR Mouse FEMALE	NOCREAM NO_SSL	VEHICLE NO_SSL	ALOGEL6% NO_ SSL	WHLEAF6% NO_ SSL	CHARCL6% NO_ SSL	AEMOD_ H NO_ SSL
Dermis, Inflammation, Chronic Active	32 (89%)	32 (89%)	35 (97%)	36 (100%)	34 (94%)	36 (100%)
Dermis, Inflammation, Granulomatous						
Edema		1 (3%)			1 (3%)	
Epidermis, Necrosis						
Hemorrhage		1 (3%)				
Hyperplasia, Squam Atypical, Focal, One						
Hyperplasia, Squamous	1 (3%)	5 (14%)	1 (3%)	4 (11%)		
Inflammation, Pyogranulomat		1 (3%)		1 (3%)		2 (6%)
Subcut Tiss, Abscess						1 (3%)
Subcut Tiss, Inflammation, Chronic						
Skin, Site Of Application	(3)	(0)	(0)	(0)	(0)	(0)
Skin, Site of Application	(33)	(36)	(36)	(36)	(36)	(36)
Abscess		1 (3%)				
Cyst						
Cyst Epithelial Inclusion	3 (9%)		2 (6%)	2 (6%)	5 (14%)	6 (17%)
Dermis, Inflammation, Chronic Active	33 (100%)	36 (100%)	36 (100%)	36 (100%)	36 (100%)	36 (100%)
Edema					1 (3%)	
Epidermis, Necrosis						
Granuloma		1 (3%)				
Hyperplasia, Squam Atypical, Focal, > Five						
Hyperplasia, Squam Atypical, Focal, Five						
Hyperplasia, Squam Atypical, Focal, Four						
Hyperplasia, Squam Atypical, Focal, One						
Hyperplasia, Squam Atypical, Focal, Three						
Hyperplasia, Squam Atypical, Focal, Two						
Hyperplasia, Squamous	1 (3%)	10 (28%)	13 (36%)	2 (6%)	1 (3%)	2 (6%)
Inflammation, Pyogranulomat						

MUSCULOSKELETAL SYSTEM

None

a - Number of animals examined microscopically at site and number of animals with lesion

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

CAS Number: ALOEPHOTOTOX

Test Type: 1-YEAR

Route: SKIN APPLICATION

Test Compound: Aloe phototoxicity studies

Date Report Requested: 10/23/2014 Time Report Requested: 13:01:44

First Dose M/F: NA / NA

Lab: NCTR

Species/Strain: Mouse/SKH-1/NCTR

SKH-1/NCTR Mouse FEMALE	NOCREAM NO_SSL	VEHICLE NO_SSL	ALOGEL6% NO_ SSL	WHLEAF6% NO_ SSL	CHARCL6% NO_ SSL	AEMOD_ H NO_ SSL
NERVOUS SYSTEM None						
RESPIRATORY SYSTEM None						
SPECIAL SENSES SYSTEM None						
URINARY SYSTEM None						

Species/Strain: Mouse/SKH-1/NCTR

Test Type: 1-YEAR

Route: SKIN APPLICATION

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Compound: Aloe phototoxicity studies

CAS Number: ALOEPHOTOTOX

Date Report Requested: 10/23/2014
Time Report Requested: 13:01:44

First Dose M/F: NA / NA

Lab: NCTR

		4				
SKH-1/NCTR Mouse FEMALE	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL	ALOGEL6% 13.7SSL	WHLEAF3% 13.75
Disposition Summary						
Animals Initially In Study	36	36	36	36	36	36
Early Deaths						
Moribund Sacrifice	1	1	1	4	4	2
Natural Death	1				1	1
Survivors						
Moribund Sacrifice	3					1
Terminal Sacrifice	24	1	2			1
Harvest	7	34	33	32	31	31
Animals Examined Microscopically	36	36	36	36	36	36
ALIMENTARY SYSTEM None						
CARDIOVASCULAR SYSTEM None						
ENDOCRINE SYSTEM None						
GENERAL BODY SYSTEM None						
GENITAL SYSTEM None						
HEMATOPOIETIC SYSTEM None						
INTEGUMENTARY SYSTEM						
Skin, Control	(36)	(36)	(36)	(36)	(36)	(36)
Abscess					3 (8%)	

a - Number of animals examined microscopically at site and number of animals with lesion

Species/Strain: Mouse/SKH-1/NCTR

Route: SKIN APPLICATION

Test Type: 1-YEAR

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Compound: Aloe phototoxicity studies

CAS Number: ALOEPHOTOTOX

Date Report Requested: 10/23/2014 Time Report Requested: 13:01:44

First Dose M/F: NA / NA

Lab: NCTR

SKH-1/NCTR Mouse FEMALE	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL
Dermis, Inflammation, Chronic Active	35 (97%)	29 (81%)	29 (81%)	30 (83%)	35 (97%)	32 (89%)
Dermis, Inflammation, Granulomatous						
Edema						
Epidermis, Necrosis		1 (3%)		2 (6%)		
Hemorrhage		1 (3%)				
Hyperplasia, Squam Atypical, Focal, One			1 (3%)	1 (3%)	1 (3%)	1 (3%)
Hyperplasia, Squamous	1 (3%)	12 (33%)	3 (8%)			
Inflammation, Pyogranulomat		1 (3%)		3 (8%)		
Subcut Tiss, Abscess			1 (3%)			
Subcut Tiss, Inflammation, Chronic		1 (3%)				
Skin, Site Of Application	(0)	(0)	(0)	(0)	(0)	(1)
Skin, Site of Application	(36)	(36)	(36)	(36)	(36)	(35)
Abscess						
Cyst			1 (3%)			
Cyst Epithelial Inclusion	6 (17%)	5 (14%)	5 (14%)	10 (28%)	5 (14%)	8 (23%)
Dermis, Inflammation, Chronic Active	36 (100%)	36 (100%)	36 (100%)	36 (100%)	36 (100%)	35 (100%)
Edema						
Epidermis, Necrosis			1 (3%)	3 (8%)		1 (3%)
Granuloma			1 (3%)		1 (3%)	
Hyperplasia, Squam Atypical, Focal, > Five	1 (3%)	5 (14%)	5 (14%)	2 (6%)	2 (6%)	2 (6%)
Hyperplasia, Squam Atypical, Focal, Five	1 (3%)	1 (3%)	4 (11%)	1 (3%)	4 (11%)	6 (17%)
Hyperplasia, Squam Atypical, Focal, Four		3 (8%)	7 (19%)	3 (8%)	3 (8%)	4 (11%)
Hyperplasia, Squam Atypical, Focal, One	10 (28%)	7 (19%)	8 (22%)	10 (28%)	10 (28%)	6 (17%)
Hyperplasia, Squam Atypical, Focal, Three	1 (3%)	8 (22%)	7 (19%)	3 (8%)	5 (14%)	5 (14%)
Hyperplasia, Squam Atypical, Focal, Two	2 (6%)	8 (22%)	4 (11%)	8 (22%)	5 (14%)	10 (29%)
Hyperplasia, Squamous	32 (89%)	36 (100%)	35 (97%)	34 (94%)	33 (92%)	35 (100%)
Inflammation, Pyogranulomat		2 (6%)	1 (3%)			2 (6%)

MUSCULOSKELETAL SYSTEM

None

a - Number of animals examined microscopically at site and number of animals with lesion

Species/Strain: Mouse/SKH-1/NCTR

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Type: 1-YEAR

Test Compound: Aloe phototoxicity studies

Route: SKIN APPLICATION

CAS Number: ALOEPHOTOTOX

Date Report Requested: 10/23/2014
Time Report Requested: 13:01:44

First Dose M/F: NA / NA

Lab: NCTR

SKH-1/NCTR Mouse FEMALE	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL
NERVOUS SYSTEM None						
RESPIRATORY SYSTEM None						
SPECIAL SENSES SYSTEM None						
URINARY SYSTEM None						

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Type: 1-YEAR

Route: SKIN APPLICATION

Species/Strain: Mouse/SKH-1/NCTR

Test Compound: Aloe phototoxicity studies
CAS Number: ALOEPHOTOTOX

Date Report Requested: 10/23/2014 Time Report Requested: 13:01:44 First Dose M/F: NA / NA

Lab: NCTR

SKH-1/NCTR Mouse FEMALE	WHLEAF6% 13.7SSL	CHARL3% 13.7SSL	CHARCL6% 13.7SSL	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
Disposition Summary						
Animals Initially In Study	36	36	36	36	36	36
Early Deaths						
Moribund Sacrifice	1		2	4	1	1
Natural Death	3	2	1		2	
Survivors						
Moribund Sacrifice						
Terminal Sacrifice						
Harvest	32	34	33	32	33	35
Animals Examined Microscopically	36	36	36	36	36	36
ALIMENTARY SYSTEM None						
CARDIOVASCULAR SYSTEM None						
ENDOCRINE SYSTEM None						
GENERAL BODY SYSTEM None						
GENITAL SYSTEM None						
HEMATOPOIETIC SYSTEM None						
INTEGUMENTARY SYSTEM						
Skin, Control Abscess	(36)	(36)	(36)	(36) 1 (3%)	(36)	(36)
Cyst Epithelial Inclusion	3 (8%)	5 (14%)	2 (6%)	3 (8%)	1 (3%)	1 (3%)

a - Number of animals examined microscopically at site and number of animals with lesion

Species/Strain: Mouse/SKH-1/NCTR

Route: SKIN APPLICATION

Test Type: 1-YEAR

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Compound: Aloe phototoxicity studies

CAS Number: ALOEPHOTOTOX

Date Report Requested: 10/23/2014 Time Report Requested: 13:01:44

First Dose M/F: NA / NA

Lab: NCTR

SKH-1/NCTR Mouse FEMALE	WHLEAF6% 13.7SSL	CHARL3% 13.7SSL	CHARCL6% 13.7SSL	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SS
Dermis, Inflammation, Chronic Active	30 (83%)	33 (92%)	29 (81%)	31 (86%)	30 (83%)	19 (53%)
Dermis, Inflammation, Granulomatous	1 (3%)					
Edema						
Epidermis, Necrosis		1 (3%)				
Hemorrhage	1 (3%)					
Hyperplasia, Squam Atypical, Focal, One			1 (3%)	1 (3%)	1 (3%)	
Hyperplasia, Squamous	1 (3%)		4 (11%)			
Inflammation, Pyogranulomat		1 (3%)	1 (3%)		1 (3%)	
Subcut Tiss, Abscess						
Subcut Tiss, Inflammation, Chronic						
Skin, Site Of Application	(0)	(0)	(0)	(0)	(1)	(0)
Skin, Site of Application	(36)	(36)	(36)	(36)	(35)	(36)
Abscess						
Cyst						
Cyst Epithelial Inclusion	1 (3%)	7 (19%)	5 (14%)	5 (14%)		2 (6%)
Dermis, Inflammation, Chronic Active	33 (92%)	35 (97%)	33 (92%)	35 (97%)	35 (100%)	32 (89%)
Edema						
Epidermis, Necrosis		4 (11%)	3 (8%)	1 (3%)	1 (3%)	3 (8%)
Granuloma	2 (6%)					
Hyperplasia, Squam Atypical, Focal, > Five	2 (6%)	1 (3%)	7 (19%)	2 (6%)	2 (6%)	7 (19%)
Hyperplasia, Squam Atypical, Focal, Five	3 (8%)		1 (3%)	3 (8%)	4 (11%)	4 (11%)
Hyperplasia, Squam Atypical, Focal, Four	6 (17%)	1 (3%)	4 (11%)	6 (17%)	5 (14%)	7 (19%)
Hyperplasia, Squam Atypical, Focal, One	5 (14%)	12 (33%)	6 (17%)	8 (22%)	6 (17%)	5 (14%)
Hyperplasia, Squam Atypical, Focal, Three	6 (17%)	9 (25%)	3 (8%)	8 (22%)	5 (14%)	5 (14%)
Hyperplasia, Squam Atypical, Focal, Two	7 (19%)	9 (25%)	6 (17%)	5 (14%)	5 (14%)	6 (17%)
Hyperplasia, Squamous	32 (89%)	34 (94%)	35 (97%)	34 (94%)	34 (97%)	34 (94%)
Inflammation, Pyogranulomat			2 (6%)	1 (3%)		

MUSCULOSKELETAL SYSTEM

None

a - Number of animals examined microscopically at site and number of animals with lesion

P03: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a)

Test Type: 1-YEAR

Route: SKIN APPLICATION

Species/Strain: Mouse/SKH-1/NCTR

Test Compound: Aloe phototoxicity studies **CAS Number:** ALOEPHOTOTOX

Date Report Requested: 10/23/2014 Time Report Requested: 13:01:44

First Dose M/F: NA / NA

Lab: NCTR

SKH-1/NCTR Mouse FEMALE	WHLEAF6% 13.7SSL	CHARL3% 13.7SSL	CHARCL6% 13.7SSL	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
NERVOUS SYSTEM None						
RESPIRATORY SYSTEM None						
SPECIAL SENSES SYSTEM None						
URINARY SYSTEM None						

** END OF REPORT **